DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-0975]

Acceptance of Medical Device Clinical Data from Studies Conducted Outside the United States; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Acceptance of Medical Device Clinical Data from Studies Conducted Outside the United States; Draft Guidance for Industry and Food and Drug Administration Staff." This draft guidance articulates FDA's current policy of accepting scientifically valid clinical data obtained from foreign clinical studies in support of premarket submissions for devices. The guidance describes special considerations that apply when using such data, including applicability to populations within the United States and study design issues and provides recommendations to assist sponsors in ensuring their data are adequate under applicable FDA standards to support approval or clearance of the device in the United States. This guidance is not intended to announce new policy, but to describe FDA's existing approach to this topic. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by **[INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Acceptance of Medical Device Clinical Data from Studies Conducted Outside the United States; Draft Guidance for Industry and Food and Drug Administration Staff" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002 or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 71, rm. 3128, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Aaliyah Eaves-Leaños, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5420, Silver Spring, MD 20993-0002, 301-796-2948. For questions regarding this document

concerning devices regulated by CBER, contact Stephen Ripley, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA), Pub. L. No 112-144 (2012), adding a new provision, section 569B, to the Federal Food, Drug, and Cosmetic Act (FD&C Act) codifying FDA's longstanding policy of accepting adequate, ethically-derived, scientifically valid data without regard to where a clinical study is conducted. Sponsors may choose to conduct multinational clinical studies under a variety of scenarios. FDA acknowledges, however, that certain challenges exist in using data derived from studies of devices from sites from outside the United States (OUS) to support an FDA marketing decision. These challenges may include differences between the OUS and US clinical conditions, regulatory requirements (including human subject protections), and/or study populations that may be sufficient to affect the adequacy of the data for use in establishing the safety and/or effectiveness of the studied device. This guidance focuses on considerations sponsors of device submissions should take into account when initiating, or relying on previously collected data from, an OUS clinical study to support an Investigational Device Exemption, Premarket Notification (510(k)), De Novo Petition, Humanitarian Device Exemption, or Premarket Approval Application. This guidance also notes other important considerations to take into account when initiating or relying on OUS data. FDA believes that promoting greater clarity concerning FDA's use of foreign study data will minimize the possibility for additional or

duplicative US studies, further efforts to harmonize global clinical trial standards, and promote public health and innovation.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on acceptance of clinical data from foreign studies conducted OUS. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Centers for Devices and Radiological Health guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov. Persons unable to download an electronic copy of "Acceptance of Medical Device Clinical Data from Studies Conducted Outside the United States; Draft Guidance for Industry and Food and Drug Administration Staff" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1741 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management

and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910-0755; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338; the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910-0485; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 812 has been approved under OMB control number 0910-0078; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910-0332; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073.

V. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: April 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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